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TITLE: Evaluating the Feasibility of RESCUE: An Adjunctive HAI-Based Intervention for Veterans with PTSD

PRINCIPAL INVESTIGATOR: Dr. Peter Tuerk

CONTRACTING ORGANIZATION: Charleston Research Institute
Charleston, SC 29403

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6. AUTHOR(S)
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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Charleston Research Institute (CRI), 176-A Ashley Avenue, Charleston, SC 29403

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13. SUPPLEMENTARY NOTES:

14. ABSTRACT
Due to award transfer and delayed funds on station the start date was 2/1/16.
This report documents accomplishment of the following tasks: 1. Consultation with and coordination among experts in combat-related PTSD, evidence based treatment (EBT), scientific design, and therapeutic Human Animal Interaction (HAI); 2. Engagement of key stakeholders (e.g., Veteran support groups, animal rescue groups) as a means of identifying potential barriers to study goals and to facilitate study recruitment; 3. Establishment of working relationship with local shelter facility staff; 4. Review of protocols/treatment materials; 5.Refinement of eligibility criteria, exclusion criteria, and screening protocol; 6. Preparation and submission of protocol to Charleston VAMC R&D and MUSC IRB, (IRB pre-approval obtained: i.e., IRB approval is secured pending submission of shelter letters of support and approval of potential HRPO revisions); 7. Recruitment, hiring, and training of study independent evaluators (IEs) (training is ongoing).

15. SUBJECT TERMS
psychotherapy; PTSD; Veterans; prolonged exposure

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER
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1. **INTRODUCTION:** PTSD is a common mental health disorder among Veterans. Currently, there are more Veterans with PTSD who do not engage in or drop-out of treatment than there are Veterans who complete treatment. Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE), is an adjunctive, Human Animal Interaction (HAI) intervention that will be developed for integration into Prolonged Exposure (PE) treatment. The goal of RESCUE is to increase emotional engagement and decrease emotional numbing, an important barrier to care, and thus improve functioning and EBT completion rates.

2. **KEYWORDS:** psychotherapy; PTSD; Veterans; prolonged exposure

3. **ACCOMPLISHMENTS:**

    - **What were the major goals of the project?**

Major Goal 1: Development of Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE) provider manuals and patient handouts, Obtain approvals from oversight bodies. Major Goal 2: Conduct a case series wherein Veterans (N=5) will be treated with the RESCUE/ PE protocol to work out any protocol/logistical difficulties and collect initial feasibility/accessibility. Major Goal 3: Test feasibility, acceptability, and initial efficacy of RESCUE/ PE in a pilot RCT conducted with Veterans (N= 50) meeting Diagnostic and Statistical Manual Fifth Edition (DSM-V) criteria for PTSD randomly assigned to RESCUE/ PE or to TAU/ Prolonged Exposure (PE) followed by RESCUE.

    - **What was accomplished under these goals?**.

a) Conducted interviews, posted study positions, and selected support staff personnel for the study, initiated training.

b) Wrote and submitted IRB, application number Pro00053520, submitted on 03/04/2016, Department pre-approval obtained on 07-MAR-2016, Department Approval Letter Issued on 08-MAR-2016. IRB pre-approval obtained (full approval pending submission of shelter letters of support and review of potential HRPO-related edits).

c) Initiated collaborative contact with HRPO officials to review initial IRB findings and requirements prior to HRPO submission.

d) Initiated contact with partner shelters.

e) Initiated contact and collaboration with Veteran stakeholder organizations.

f) Initiated purchasing of study supplies.

g) Gathering and creating study materials (fidelity forms, patient binders, MoP, etc.)

h) Initiated consultation regarding Human Animal Interaction (HAI)

i) Study presented at symposium: “Human-Animal Interactions in Treating Veterans with PTSD” American Psychological Association (APA) 123rd Annual Convention on 09-AUG-2015, Toronto, Canada.

See Chart for specific aims related to reporting period:

Specific Aim 1: Development of Recovery through Engagement with Shelter Canines, Understanding, and Exposure (RESCUE) provider manuals and patient handouts, Obtain approvals from oversight bodies.	**Timeline/ Months**	**Percentage Complete**
Major Task 1: Knowledge elicitation from consulting experts and key stakeholders.		
Consult experts in combat-related PTSD, Empirically Based Treatment (EBT), behaviorism, and therapeutic Human Animal Interaction (HAI)	0-2	90%
Engage key stakeholders as a means of identifying potential treatment barriers and to facilitate study recruitment later.	0-2	100%
Established/continue working relationship with local SPCA facility staff .	0-36	100%
Major Task 2: Finalize treatment and control protocols		
Review of protocols/treatment materials by consulting experts in combat-related PTSD treatment and Human Animal Interaction (HAI) /animal behaviorism for theoretical soundness, usability, and quality.	0-3	80%
Major Task 3: Obtain IRB approval		
Develop eligibility criteria, exclusion criteria, and screening protocol	0-3	100%
Develop consent form and human subjects protocol	0-3	100%
Prepare and submit protocol to Charleston VAMC R&D and MUSC IRB	0-4	100%
Submit IRB protocol to DOD/HRPO	0-4	0%
Obtain IRB, R&D, and HRPO approvals to move forward	0-6	50%
Submit amendments, adverse events and protocol deviations as needed	0-36	100%
Submit annual IRB report for continuing review (local)	0-36	100%
Submit annual IRB report for continuing review and reports to HRPO as needed.	0-36	100%
Major Task 4: Recruit & train IEs and study therapists		
Recruit, facilitate hiring, and train study independent evaluators (IEs)	0-6	100%
Facilitate and coordinate training and PE certification, supervision, and fidelity checks as needed for project therapists.	0-6	50%
Specific Aim 2: A case series wherein Veterans (N=5) will be treated		
Major Task 1: Finalize Thematic Interview Measures/Focus group procedures		
Synthesize thematic interview based on scientific- and key stakeholder-knowledge	0-6	100%
Major Task 2: Recruit combat Veterans with PTSD for case series		
Utilize PTSD Clinical Team (PCT) developed referral stream for study recruitment	6 - 8	20%
Major Task 3: Conduct pre-treatment evaluations for case series		
Screen, obtain consent, assess, and enroll participants	6 - 8	0%
Major Task 4: Conduct RESCUE/PE treatment with case series participants		
Conduct and complete case series for additional refinements in design, logistics,	6-10	0%
Major Task 5: Conduct post-treatment evaluations for case series participants		
Complete post-treatment standardized evaluations and clinical interviews.	8-10	0%
Complete post-treatment 60-minute thematic interviews/focus groups.	8-10	0%
Major Task 6: Data review and Refinement of protocol and materials		
Consulting experts review randomly selected sessions	8 - 11	0%
Review and analysis of thematic interview outcomes	8 - 11	0%
Review and analysis of quantitative case report measures	8 - 11	0%
Protocol refinement as indicated	11	0%

- **What opportunities for training and professional development has the project provided?**
    - Nothing to report.
- **How were the results disseminated to communities of interest?**
    - Nothing to report.
- **What do you plan to do during the next reporting period to accomplish the goals?**

1. Submit IRB protocol to DOD/HRPO
2. Finalize IRB, R&D, and HRPO approvals to move forward
3. Continue training study independent evaluators (IEs)
4. Facilitate and coordinate training and PE certification, supervision, and fidelity checks as needed for project therapists.
5. Finalize thematic interview based on scientific- and key stakeholder-knowledge gained in Specific Aim 1. Construct thematic interview protocol in line with established procedures for best practices qualitative research.
6. Utilize PTSD Clinical Team (PCT) to develop referral stream for study
7. Screen, obtain consent, assess, and enroll participants for pilot and RCT.

4. **IMPACT:**
    - **What was the impact on the development of the principal discipline(s) of the project?**
        - Nothing to report.
    - **What was the impact on other disciplines?**
        - Nothing to report.
    - **What was the impact on technology transfer?**
        - Nothing to report.
    - **What was the impact on society beyond science and technology?**
        - Nothing to report.
5. **CHANGES/PROBLEMS:**
    - **Changes in approach and reasons for change**
        - Nothing to report.
    - **Actual or anticipated problems or delays and actions or plans to resolve them**

1. Staff at area shelters turned over and so new relationships had to be forged, this is not a significant issue.
2. We had originally planned on submitting to HRPO in the first quarter but delays in getting funds on station (funds will cover a start date of 01-FEB-2016) and longer than anticipated local IRB review has delayed this goal. We did promptly submit to local IRB, obtained preliminary approval, and will commence HRPO review in the coming weeks. We have already established contact with HRPO staff who have been very responsive and we do not anticipate any difficulties in the collaborative relationship.

- **Changes that had a significant impact on expenditures**

First quarter funds were received in early April and will be used to cover staff effort, consultation services, and equipment/supplies. Our local research institute has drawn up subaward agreements and we expect them to be fully executed in the coming weeks. Once they are in place, we expect to be invoiced for salaries and fringe since February 1.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**
  - Nothing to report.
- **Significant changes in use or care of human subjects**
  - Not applicable.
- **Significant changes in use or care of vertebrate animals.**
  - Not applicable.
- **Significant changes in use of biohazards and/or select agents**
  - Not applicable.

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**

Study presented at symposium: "Human-Animal Interactions in Treating Veterans with PTSD" American Psychological Association (APA) 123rd Annual Convention on 09-AUG-2015, Toronto, Canada.

- **Journal publications.** Nothing to report.
- **Books or other non-periodical, one-time publications.** Nothing to report.
- **Other publications, conference papers, and presentations.** Nothing to report.
- **Website(s) or other Internet site(s)**
  Nothing to report.
- **Technologies or techniques**
  Nothing to report.
- **Inventions, patent applications, and/or licenses**
  Nothing to report.

- **Other Products**
  - Not applicable.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

- **What individuals have worked on the project?**

Name:	Dr. Peter Tuerk
Project Role:	PI
Nearest person month worked:	3
Contribution to Project:	Consulted with experts in therapeutic Human Animal Interaction (HAI). Engaged key stakeholders (e.g., Veteran support groups, animal rescue groups) as a means of identifying potential treatment barriers and to facilitate study recruitment. Reviewed protocols/treatment materials. Developed eligibility criteria, exclusion criteria, and screening protocol. Prepared and submitted protocol to Charleston VAMC R&D and MUSC IRB. Recruited, facilitated hiring, and training study independent evaluators (IEs) (staff recruited, training is ongoing).

Name:	Dr. Ronald Acierno
Project Role:	Co-I
Researcher Identifier (e.g. ORCID ID):	0000-0001-8799-8210
Nearest person month worked:	1
Contribution to Project:	Provided consultation on MUSC IRB. Assisted with protocol development.

Name:	Dr. Donald L. Myrick
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Provided consultation on MUSC IRB. Assisted with protocol development.

Name:	Dr. Bethany Wangelin
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Reviewed protocols/treatment materials. Developed eligibility criteria, exclusion criteria, and screening protocol. Prepared and submitted protocol to Charleston VAMC R&D and MUSC IRB.

Name:	Dr. Kristy Center
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Engaged key stakeholders (e.g., Veteran support groups, animal rescue groups) as a means of identifying potential treatment barriers and to facilitate study recruitment. Established working relationship with local shelter facility staff.

Name:	Dr. Brian Lozano
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Reviewed protocols/treatment materials. Developed eligibility criteria, exclusion criteria, and screening protocol. Prepared and submitted protocol to Charleston VAMC R&D and MUSC IRB.

Name:	Dr. Anouk Grubaugh
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Consulted with experts in combat-related PTSD, Empirically Based Treatment (EBT), behaviorism, and therapeutic Human Animal Interaction (HAI).

Name:	Dr. Michael Kolfer
Project Role:	Co-I
Nearest person month worked:	1
Contribution to Project:	Consultation regarding human animal interaction (HAI) aspect of trial.

Name:	Ursula Myers, M.S.
Project Role:	Lab coordinator
Nearest person month worked:	1
Contribution to Project:	Prepared and submitted protocol to Charleston VAMC R&D and MUSC IRB.

Name:	Bridgette Niepoth, M.S.
Project Role:	Research Assistant II
Nearest person month worked:	6
Contribution to Project:	Prepared and submitted protocol to Charleston VAMC R&D and MUSC IRB.

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- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**

Dr. Tuerk has received additional support on the following grants:

R42MH094019-04; Tuerk (PI) 9/16/11 - 8/31/17; 2.25 CM
Pegasys VR: Integrating Virtual Humans in the Treatment of Child Social Anxiety

PT140178- USA MED RESEARCH ACQ ACTIVITY; Foa (PI) 09/30/15-09/29/18; 1.2 CM
The Efficacy of 90-minute vs 60-minute sessions of Prolonged Exposure for PTSD: A Randomized Control Trial in Active Duty Military Personnel.

Funding on the following grants has expired for Dr. Tuerk:

VA-CDA-2-0003; Tuerk (PI) 07/01/2010-06/30/2015; 9.0 CM Prolonged Exposure for PTSD with and without Yohimbine and the Correlates of Trait Habituation

- **What other organizations were involved as partners?**
  - Not applicable.

7. **SPECIAL REPORTING REQUIREMENTS**
   - **COLLABORATIVE AWARDS:**
     - Not applicable.
   - **QUAD CHARTS:** If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.
8. **APPENDICES:** Not applicable.

Evaluating the Feasibility of RESCUE: An Adjunctive HAI-Based Intervention for Veterans with PTSD

Log Number: 13046027
Award Number: W81XWH-15-1-0087

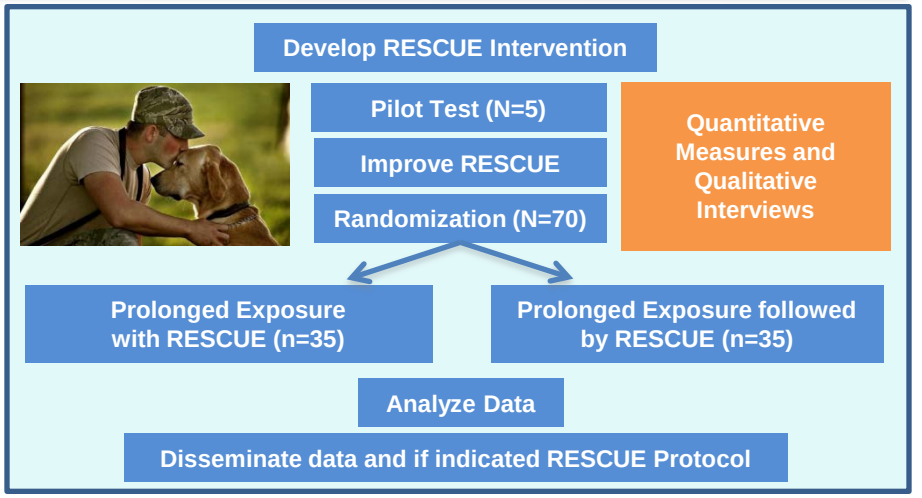
PI: Peter W. Tuerk, Ph.D. **Org:** Charleston Research Institute/Ralph H. Johnson VAMC **Award Amount:** $709,517

Study/Product Aim(s)

- To develop and pilot test feasibility, acceptability, and efficacy of RESCUE, an adjunct scalable human animal interaction (HAI) intervention involving shelter dogs for use with disseminated Empirically Based Treatments (EBT) for posttraumatic stress disorder (PTSD) to increase treatment engagement and completion.

Approach

The project is organized into 3 sequential phases/aims. (1) Development of treatment protocols; (2) A case series wherein 5 Veterans will be treated with Prolonged Exposure (PE) therapy in tandem with the experimental RESCUE component to work out protocol/logistical difficulties and collect initial feasibility and accessibility data; and (3) a randomized controlled trial using a crossover design with 50 Veterans (recruit 70) with PTSD randomized to PE simultaneously with RESCUE or PE followed by RESCUE. Outcomes will include subjective PTSD assessments, objective PTSD assessments, and qualitative interviews.



Accomplishments: Recruited study staff, initiated development of RESCUE protocol, created study materials, submitted to Internal Review Board (IRB), initiated outreach to partner and stakeholder organizations.

Timeline and Cost

Activities CY	16	17	18
Develop treatment			
Pilot test treatment and revamp			
Conduct RCT			
Analyze data			
Disseminate findings & study knowledge			
Estimated Budget ($K)	**$249,000**	**$230,000**	**$230,000**

Updated: 5/23/16

Goals/Milestones

CY16 Goals – Treatment development & test pilot
☑Develop treatment protocols
☑Develop thematic interviews
☑Conduct outreach to partner and stakeholder organizations
❑Complete pilot case series
❑Revamp protocol as indicated by data

CY17 Goals –Randomized controlled trial of treatment (N=70)
☐ Recruit and consent 52 participants
☐ Complete treatment and assessments

CY18 Goal – Complete trial, analyze data, disseminate findings
☐ Recruit and consent 18 participants
☐ Complete treatment and assessments
☐ Analyze data
☐ Disseminate findings.

Comments/Challenges/Issues/Concerns: None
Budget Expenditure to Date: Have not received funds on station yet.
Projected Expenditure: Budget period 2/1/2016 - 1/31/2017: $248,444